Open Disclosure Policy and Procedure

Policy Risk Rating = (10)

Open disclosure is a discussion and an exchange of information that may take place in one conversation or over one or more meetings. Open disclosure should be timely information that is communicated accurately and sensitively

Open disclosure does not, of itself, create legal liability. Acknowledging an adverse event, apologising or expressing regret, is not an admission of liability.

Open Disclosure is enacted when:

When health care does not go to plan, evidence suggests that patients want to know and understand what happened and why. They want to feel there is genuine regret that the event occurred and they want to know that steps will be taken to minimise the risk of similar events occurring again.

This is assigned to:

- DON
- Nursing staff
- General Manager is the complaints person
- VMO's

Procedure

A discussion template and an open disclosure checklist are available on the Perioperative share drive.
A Statutory Duty of Candour (SDC) - Checklist for SDC process, Statutory Duty of Candour (SDC) - Initial meeting 'note' template and Statutory Duty of Candour (SDC) - Meeting report template are available on the Perioperative share drive.

PRINCIPLES OF OPEN DISCLOSURE

1. **Open and timely communication**
   If things go wrong, the patient, their family and carers should be provided with information about what happened in a timely, open and honest manner. The open disclosure process is fluid and will often involve the provision of ongoing information.

2. **Acknowledgement**
   All adverse events should be acknowledged to the patient, their family and carers as soon as practicable. Health service organisations should acknowledge when an adverse event has occurred and initiate open disclosure procedure

3. **Apology or expression of regret**
   As early as possible, the patient, their family and carers should receive an apology or expression of regret for any harm that resulted from an adverse event. An apology or expression of regret should include the words 'I am sorry' or 'we are sorry', but must not contain speculative statements, admission of liability or apportioning of blame.

4. **Supporting, and meeting the needs and expectations of patients, their family and carer(s)**
   The patient, their family and carers can expect to be:
   - fully informed of the facts surrounding an adverse event and its consequences
   - treated with empathy, respect and consideration
   - supported in a manner appropriate to their needs.

5. **Supporting, and meeting the needs and expectations of those providing health care**
   Health service organisations should create an environment in which all staff are:
   - encouraged and able to recognise and report adverse events
   - prepared through training and education to participate in open disclosure
   - supported through the open disclosure process.
   -

6. **Integrated clinical risk management and systems improvement**
   Thorough clinical review and investigation of adverse events and adverse outcomes should be conducted through processes that focus on the management of clinical risk and quality improvement.

   Outcomes of these reviews should focus on improving systems of care and be reviewed for their effectiveness. The information obtained about incidents from the open disclosure process should be incorporated into quality improvement activity

7. Good governance

Open disclosure requires good governance frameworks, and clinical risk and quality improvement processes. Through these systems, adverse events should be investigated and analysed to prevent them recurring.
Good governance involves a system of accountability through a health service organisation's senior management, executive or governing body to ensure that appropriate changes are implemented and their effectiveness is reviewed. Good governance should include internal performance monitoring and reporting.

8. Confidentiality

Policies and procedures should be developed by health service organisations with full consideration for patient and clinician privacy and confidentiality, in compliance with relevant law (including federal, state and territory privacy and health records legislation). However, this principle needs to be considered in the context of *Principle 1: Open and timely communication.*

KEY ELEMENTS OF THE OPEN DISCLOSURE PROCESS

1. Detecting and assessing incidents

- Detect adverse event through a variety of mechanisms
- Provide prompt clinical care to the patient to prevent further harm
- Assess the incident for severity of harm and level of response
- Provide support for staff
- Initiate a response, ranging from lower to higher levels
- Notify relevant personnel and authorities
- Ensure privacy and confidentiality of patients and clinicians are observed

2. Signaling the need for open disclosure

- Acknowledge the adverse event to the patient, their family and carers including an apology or expression of regret.
- A lower level response can conclude at this stage.
- Signal the need for open disclosure
- Negotiate with the patient, their family and carers or nominated contact person
    - the formality of open disclosure required
    - the time and place for open disclosure
    - who should be there during open disclosure
- Provide written confirmation
- Provide a health service contact for the patient, their family and carers
- Avoid speculation and blame
- Maintain good verbal and written communication throughout the open disclosure process

3. Preparing for open disclosure

- Hold a multidisciplinary team discussion to prepare for open disclosure
- Consider who will participate in open disclosure
- Appoint an individual to lead the open disclosure based on previous discussion with the patient, their family and carers
- Gather all the necessary information
- Identify the health service contact for the patient, their family and carers (if this is not done already)

4. Engaging in open disclosure

- Provide the patient, their family and carers with the names and roles of all attendees
- Provide a sincere and unprompted apology or expression of regret including the words I am or we are sorry
- Clearly explain the incident
- Give the patient, their family and carers the opportunity to tell their story, exchange views and observations about the incident and ask questions
- Encourage the patient, their family and carers to describe the personal effects of the adverse event
- Agree on, record and sign an open disclosure plan
- Assure the patient, their family and carers that they will be informed of further investigation findings and recommendations for system improvement
- Offer practical and emotional support to the patient, their family and carers
- Support staff members throughout the process
- If the adverse event took place in another health service organisation, include relevant staff if possible.

- If necessary, hold several meetings or discussions to achieve these aims

5. Providing follow-up

- Ensure follow-up by senior clinicians or management, where appropriate
- Agree on future care
- Share the findings of investigations and the resulting practice changes
- Offer the patient, their family and carers the opportunity to discuss the process with another clinician (e.g. a general practitioner)

6. Completing the process

- Reach an agreement between the patient, their family and carers and the clinician, or provide an alternative course of action
- Provide the patient, their family and carers with final written and verbal communication, including investigation findings
- Communicate the details of the adverse event, and outcomes of the open disclosure process, to other relevant clinicians
- Complete the evaluation surveys

7. Maintaining documentation

- Keep the patient record up to date
- Maintain a record of the open disclosure process
- File documents relating to the open disclosure process in the patient record
- Provide the patient with documentation throughout the process

KEY COMPONENTS OF OPEN DISCLOSURE DISCUSSIONS

1. Introductions

- The patient, their family and carers is told the name and role of everyone attending the meeting, and this information is also provided in writing.

2. Saying sorry

A sincere and unprompted apology or expression of regret is given on behalf of the healthcare service and clinicians, including the words 'I am' or 'we are sorry'. Examples of suitable and unsuitable phrasing of an apology are provided in the resource titled Saying Sorry: a guide to apologising and expressing regret in open disclosure available at www.safetyandquality.gov.au/opendisclosure

3. Factual explanation: providers

A factual explanation of the adverse event is provided, including the known facts and consequences of the adverse event, in a way that ensures the patient, their family and carers understand the information, and considers any relevant information related earlier by the patient, family and carers. Speculation should be avoided.

4. Factual explanation: patient, family and carer(s)

The patient, family and carers have the opportunity to explain their views on what happened, contribute their knowledge and ask questions (the patient's factual explanation of the adverse event). It will be important for the patient, their family and carers that their views and concerns are listened to, understood and considered.

5. Personal effect of the adverse event

The patient, family and carers is/are encouraged to talk about the personal effect of the adverse event on their life.

6. Plan agreed and recorded

An open disclosure plan is agreed on and recorded, in which the patient, their family and carer(s) outline what they hope to achieve from the process and any questions they would like answered. This is to be documented and filed in the appropriate place and a copy provided to the patient, their family and carers.

7. Pledge to feedback

The patient, their family and carers is assured that they will be informed of any further reviews or investigations to determine why the adverse event occurred, the nature of the proposed process and the expected time frame. The patient, their family and carers are given information about how feedback will be provided on the investigation findings, by whom and in what timeframe, including any changes made to minimise the risk of recurrence.

8. Offer of support

An offer of support to the patient, their family and carers should include:

- ongoing support including reimbursement of out-of-pocket expenses incurred as a result of the adverse event
- assurance that any necessary follow-up care or investigation will be provided promptly and efficiently
- in the relevant settings, clarity on who will be responsible for providing ongoing care resulting from the adverse event
- contact details for any relevant service they wish to access information about how to take the matter further, including any complaint processes available to them

9. Support for patients and staff

The patient, their family, or carers, engage in open disclosure with staff. Staff are supported by their colleagues, managers and health service organisation, both personally (emotionally) and professionally, including through appropriate training, preparation and debrief.

10. Other health service organisations

In cases where the adverse event spans more than one location or service, relevant clinicians and staff will ensure, where possible, that all relevant staff from these additional institutions are involved in the open disclosure process.

OTHER CONSIDERATIONS:

It is not necessary to cover every component in the first disclosure meeting. For instance, a full explanation of why an adverse event occurred may not be possible until associated investigations are completed and the causative factors are known.

A written account of the open disclosure meeting should be provided to the patient, their family and carers and a copy filed in the patient record.

Monitoring and compliance

The open disclosure process is integrated into the day to day function of VSC Day Surgery and is monitored through the areas identified in processes documented in order to maintain, improve and comply with relevant regulatory authorities and best practice standards.

A comprehensive facility wide risk assessment of the facility was undertaken initially to establish risk levels for all standards. Compliance with the policy standard is monitored through the internal audit schedule and any issues raised are addressed in accordance with IIIR procedure.

VSC Day Surgery encourages and seeks feedback from patients through distribution of electronic feedback surveys. Any complaints received, via the survey or other means, are handled in accordance with the complaints' guidelines.

SAPSE

A serious adverse patient safety event (SAPSE) is an event that: occurred while the patient was receiving care from a health service entity.

If a patient suffers a SAPSE in the course of receiving health services, the health service entity responsible for providing the service owes a SDC to the patient and must do the following unless the patient has opted out:

(a) provide the patient with:

i. a written account of the facts regarding the SAPSE;

ii. an apology for the harm suffered by the patient;

iii. a description of the health service entity's response to the event;

iv. the steps that the health service entity has taken to prevent re-occurrence of the event;

v. any prescribed information; and

(b) comply with any steps set out in these Guidelines

Open Disclosure Policy and Procedure

Stage 1: Apologise and provide initial information

- Requirement 1: The health service entity must provide a genuine apology for the harm suffered by the patient and initial information, as early as practicable (and no longer than 24 hours) after the SAPSE has been identified by the health service entity.
- Requirement 2: The health service entity must take steps to organise an SDC meeting within 3 business days of the SAPSE being identified by the health service entity.

Stage 2: Hold the SDC meeting

- Requirement 3: The SDC meeting must be held within 10 business days of the SAPSE being identified by the health service entity.
- Requirement 4: The health service entity must ensure that it provides the following in the SDC meeting:
    - an honest, factual explanation of what occurred in a language that is understandable to the patient;
    - an apology for the harm suffered by the patient;
    - an opportunity for the patient to relate their experience and ask questions;
- Requirement 4: The health service entity must ensure that it provides the following in the SDC meeting:
    - an honest, factual explanation of what occurred in language that is understandable to the patient;
    - an apology for the harm suffered by the patient;
    - an opportunity for the patient to relate their experience and ask questions;
    - an explanation of the steps that will be taken to review the serious adverse patient safety event (SAPSE) and outline any immediate improvements already made; and
    - any implications as a result of the SAPSE (if known) and any follow up for the patient.
- Requirement 5: The health service entity must document the SDC meeting and provide a copy of the meeting report to the patient within 10 business days of the SDC meeting.

Stage 3: Complete a review of the SAPSE and produce report

- Requirement 6: The health service entity must complete a review for the SAPSE and produce a report outlining what happened and any areas identified for improvement. If the SAPSE is classified as a sentinel event, the health service entity must also outline in the report clear recommendations from the review findings.
- Requirement 7: The report created from Requirement 6 must then be offered to the patient within 50 business days of the SAPSE being identified by the health service entity. If the SAPSE involves more than one health service entity, this may be extended to 75 business days of the SAPSE being identified by the initial health service entity.

Documentation and reporting

- Requirement 8: The health service entity must ensure that there is a record of the SDC being completed, including clear dates of when the SAPSE occurred and when each stage of the SDC was completed.
- Requirement 9: The health service entity must report its compliance with the SDC as legally required.

VSC Day Surgery staff complete the Safer Care Victoria SAPSE online education.

Documents and records needed for this procedure, and how are they stored.

Document Title/Form Number	Paper or Electronic	Where are they kept	How long form (years)	Access restrictions	Comments
BOM Minutes	P/E	Perioperative share drive	7 years	DON/CEO/MAC	
Checklist for SDC process	E	Perioperative share drive	7 years	DON/CEO	
Open Disclosure Policy	P/E	Perioperative share drive	7 years	All staff	

IIIR Summary	P/E	Perioperative share drive	7 years	All staff	
IIIR	P/E	Perioperative share drive	7 years	All staff	
Risk Matrix	P/E	Perioperative share drive	7 years	All staff	
Statutory duty of Candour (SDC) - Meeting report template	E	Perioperative share drive	7 years	DON/CEO	
Statutory duty of Candour (SDC) - Meeting template	E	Perioperative share drive	7 years	DON/CEO	
SDC - Initial meeting note template	E	Perioperative share drive	7 years	DON/CEO	
Victorian Duty of Candour Guidelines	E	Perioperative share drive	7 years	DON/CEO	

References

National Safety and Quality Open Disclosure Framework. Australian Commission on Safety and Quality in Health Care: www.safetyandquality.gov.au/opendisclosure

Protections for serious adverse patient safety event (SAPSE) reviews - https://www.safercare.vic.gov.au/report-manage-issues/sentinel-events/adverse-event-review-and-response/duty-of-candour

Victorian Duty of Candour Guidelines, August 2022